

REMARKS/ARGUMENTS

Upon entry of the amendments submitted herewith, claims 1-9 will be pending in this application. Claims 1-3 are under examination. Claims 4-9 have been withdrawn as being drawn to non-elected subject matter. In the outstanding Office Action, the Examiner objected to the Abstract due to informalities; claims 1-2 are rejected under 35 U.S.C. §102(b) over US Patent Publication 2002/0065256 to Karlsson et al. (“Karlsson”). Claims 1-3 are rejected under 35 U.S.C. §103(a) over Karlsson in view of the Shin Etsu Material Data Safety Sheet for Metolose 60SH (“MSDS”).

By this Response and Amendment, Applicants have amended the abstract and claim 1 to more clearly describe the claimed subject matter. Support for the amendments is found in the original as-filed specification. For example, in original claim 1. Applicants respectfully submit that the amendments submitted herewith do not add any new matter within the meaning of 35 U.S.C. §132 to the application.

Accordingly, entry of the above amendments is respectfully requested.

Informalities

The Examiner objected to the abstract for reciting non-elected subject matter. By this Response and Amendment, the phrases objected to by the Examiner have been removed from the Abstract thereby rendering the objection moot.

Anticipation Rejection of Claims 1-2 under 35 U.S.C. §102(b)

The Official Action at page 3 states that claims 1-2 are rejected under 35 U.S.C. §102(b) over US Patent Publication 2002/0065256 to Karlsson et al. (“Karlsson”). Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of*

California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Karlsson appears to achieve a sterile glucocorticoid aqueous solution by heat treating glucocorticoid as a dry or lyophilized powder before it is added to an aqueous suspension. For example, see paragraphs [12] and [13], and claim 15. Karlsson's methods do not appear to teach or suggest sterilizing aqueous suspensions of glucocorticoids while they are in aqueous suspension. Moreover, Karlsson expressly teaches away from the claimed subject matter by teaching that heating aqueous suspensions of glucocorticoids results in unfavorable changes, such as clumping of particles. See paragraphs [0003] and [0009].

Applicants have amended claim 1 to more clearly describe the claimed subject matter. Namely, that the claimed subject matter involves sterilizing an aqueous ciclesonide-containing suspension, and does not recite heating of dry or lyophilized ciclesonide compositions. More particularly, the cited document does not teach sterilizing an aqueous ciclesonide-containing suspension while the ciclesonide is contained in an aqueous suspension.

Accordingly, applicants respectfully request reconsideration and withdrawal of this rejection.

Obviousness Rejections of Claims 1-3 Under 35 U.S.C. §103(a)

By this Response and Amendment, Applicant respectfully traverses the prior art rejections since all of the elements of the presently claimed subject matter are not disclosed, taught or suggested by the cited prior art. To establish a *prima facie* case of obviousness, the Examiner must establish that the prior art references teach or suggest all of the claim features. *Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d

1016, 1023 (Fed. Cir. 1991); *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970).

Claims 1-3 are rejected under 35 U.S.C. §103(a) over Karlsson in view the Shin Etsu Material Data Safety Sheet for Metolose 60SH (“MSDS”). The Examiner asserts that it “would have been customary for an artisan of ordinary skill to employ the optimal grade hydroxypropylmethylcellulose within the [Karlsson] composition in order to best achieve the desired results. Applicants traverse this rejection because none of the cited prior art references, alone or in combination, teaches or suggests sterilizing an aqueous ciclesonide-containing suspension while the ciclesonide is contained in an aqueous suspension.

In contrast to the presently claimed subject matter, and as discussed above in response to the anticipation rejection, Karlsson appears to achieve a sterile glucocorticoid aqueous solution by heat treating glucocorticoid as a dry or lyophilized powder before it is added to an aqueous suspension. For example, see paragraphs [12] and [13], and claim 15. Karlsson’s methods do not appear to teach or suggest sterilizing aqueous suspensions of glucocorticoids while they are in aqueous suspension. Moreover, Karlsson expressly teaches away from the claimed subject matter by teaching that heating aqueous suspensions of glucocorticoids results in unfavorable changes, such as clumping of particles. See paragraphs [0003] and [0009]. Further, this limitation is not shown in any way by the MSDS reference.

Since all of the features of the present claims are not disclosed, taught or suggested by the cited prior art references, alone or in any combination, the cited prior art does not render the presently claimed subject matter obvious. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the outstanding rejections.

CONCLUSION

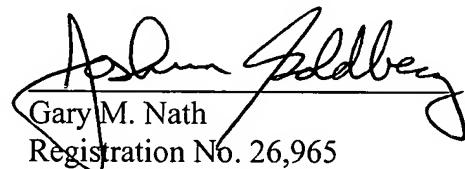
In light of the foregoing, Applicant submits that the application is now in condition for allowance. If the Examiner believes the application is not in condition for allowance, Applicant respectfully requests that the Examiner contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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